



Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221
September 11, 2003



Mr. Mike Lipscomb
Washington TRU Solutions
P.O. Box 2078
Carlsbad, NM 88221-2078

RE: Issuance of Draft CARs 03-078 Through 03-080 Initiated During Audit A-03-23 of WTS Safety and Health

Dear Mr. Lipscomb:

The Carlsbad Field Office (CBFO) performed Audit A-03-23 of Washington TRU Solutions LLC (WTS) on September 8-9, 2003. The scope of this audit was the WTS Safety and Health Organization implementation of applicable Quality Assurance requirements defined in ASME/NQA-1, 1989 edition, and the CBFO and WTS Quality Assurance Program Documents (QAPDs). As a result of this audit, the subject Corrective Action Reports (CARs) have been issued.

Please determine and document on the enclosed CAR continuation sheets your proposed corrective action plans for the CARs. Please forward proposed corrective action plans and schedules for completion of CAR 03-080 to me prior to the response due date identified in CAR block 14. CARs 03-078 and 03-079 do not require a corrective action plan. Please send completion documentation to me by the due date listed in CAR block 14 for these CARs.

If you have any questions or comments, please contact me at (505) 234-7442.

Sincerely,

M. Lea Chism
Quality Assurance Specialist

Enclosure

cc: w/enclosure
A. Holland CBFO *ED
M. Eagle, EPA *ED
B. Walker, EEG *ED
D. Winter, DNFSB *ED
S. Zappe, NMED *ED
N. Frank, CTAC *ED
J. Field, CTAC *ED
A. Pangle, CTAC *ED
J. Hoff, WTS *ED
B. Brown, WTS *ED
L. Will, WTS
K. Dunbar, WRES
CBFO QA File
CBFO M&RC
CBFO:QA:MLC:GS:03-2563:UFC 2300.00

030913



INSTRUCTIONS FOR PROVIDING CORRECTIVE ACTION RESPONSE

WASTE ISOLATION PILOT PLANT
U.S. DEPARTMENT OF ENERGY
Carlsbad Field Office

CAR NO: 03-78, 03-79, 03-80
PAGE 1 OF 1

INSTRUCTIONS FOR COMPLETING A CORRECTIVE ACTION RESPONSE TO A CAR ADDRESSING A CONDITION ADVERSE TO QUALITY

You are requested to provide a corrective action in response to this corrective action report (CAR) by the due date identified in block 14 of the CAR. If this date cannot be met, provide a written request for extension to the assessment team leader (block 5). This request must include justification for the delay and must be provided prior to the due date.

The response shall address the corrective actions indicated in block 12. As appropriate, develop the response in accordance with the following sequence and format:

In order to develop the CAR response, perform an investigative action to determine the extent and impact of the deficiency and to identify the root cause. Next, determine the actions required to correct the adverse condition. The response shall include the following information, as appropriate to block 12.

1. Corrective action response for CAR # _____
 - A. **Remedial Action**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during the investigations.
 - B. **Extent and Impact of the Deficiency**-Describe the investigative actions performed to determine the extent and impact of the condition and the results. This will include a determination of the acceptability of any data generated prior to resolution of the deficiency.
 - C. **Root Cause Determination**-Identify the root cause of the condition as determined through investigative action.
 - D. **Corrective Action to Preclude Recurrence**-Identify the actions required to address the root cause of the condition in order to preclude recurrence.
2. For each action above, identify the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.
3. The response must identify the individual having the overall responsibility for completion of the corrective actions.

CORRECTIVE ACTION REPORT

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--------------------------------|--------------------------------------------------------|------------------------------|--|
| 1. CAR No: 03-078 | | 2. Activity Report No: A-03-23 | | 3. Page <u>1</u> of <u>2</u> | |
| 4. Controlling Document: WP 12-RL.01, R7 | | | 5. CBFO Assessment Team Leader: M. Lea Chism | | |
| 6. Responsible Organization: WTS | | | 7. CAQ Was Discussed With: M. Akbarzadeh, G. Whiteford | | |
| 8. Requirement that was violated: Subsection 3.4: "There are three types of conditions requiring corrective action. They are nonconformance, variance, and conditions adverse to quality. Nonconforming items or materials are those which do not conform to specified requirements or whose conformance is indeterminate." Paragraph 3.3.1: "Audit results and recommendations are reported in writing to the Laboratories Manager for review and corrective action, if necessary. A maximum of 30 days is given to respond to the original report...The QA Officer will follow up by verifying the effectiveness of the implemented corrective action." | | | | | |
| 9. Condition Adverse to Quality: Existing controls for conditions adverse to quality were not being used by WIPP Laboratories. See attached continuation form for details. | | | | | |
| 10. Suggested Actions (Optional): None | | | | | |
| 11a. Significant CAQ | | (Yes or No): No | | | |
| 11b. Work Suspension Recommended | | (Yes or No): No | | | |
| 11c. RCRA-Related | | (Yes or No): No | | | |
| 11d. Accelerated Corrective Action Required | | (Yes or No): No | | | |
| 12. Types of Actions: Remedial: <u>X</u> Investigative: <u> </u> Root Cause: <u> </u> Actions to Preclude Recurrence: <u>X</u> | | | | | |
| 13. CAR Initiator: <u>N. Frank</u> Date: <u>9/10/03</u> | | | | | |
| 14. Response Due Date: <u>10/2/03</u> Corrective Action Plan Required: <u>NO</u> Required Corrective Action Completion Date: <u>N/A</u> | | | | | |
| 15. a. Concurrence: <u>Lea Chism</u> <u>09-11-03</u> b. <u>N/A</u> Assessment Team Leader Date Responsible Assistant Manager Date c. <u>N/A</u> Quality Assurance Manager Date | | | | | |
| 16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet | | | | | |
| 17. Acceptance of Proposed Corrective Actions: Assessment Team Leader Date | | | | | |
| 18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet) | | | | | |
| 19a. Verified By: <u> </u> <u> </u> Name Date 19b. Trend Cause Code: <u> </u> | | | | | |
| 20. Closure: <u> </u> <u> </u> Quality Assurance Manager Date | | | | | |

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No: 03-078

2. Activity No: A-03-23

3. Page 2 of 2

Block # 9 : Condition Adverse to Quality (continued)

Existing controls for conditions adverse to quality were not being used by WIPP Laboratories.

1. Items and samples that are found to be nonconforming (e.g., label does not match the chain of custody) are not controlled by the NCR process. They are not tagged or segregated from other samples. NCR is only written after in-house investigation cannot resolve the problem.
2. Conditions adverse to quality identified during the annual management assessment are not entered into a formal tracking system. Informal list was not complete (required revision to WP 12-RL1400 was not included). NCR and CAR systems are not used to document concerns.

CORRECTIVE ACTION REPORT

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| 1. CAR No: 03-079 | | 2. Activity Report No: A-03-23 | | 3. Page <u>1</u> of <u>2</u> | |
| 4. Controlling Document: WP 12-RL.01, R7 and WP 12-5, Rev. 9 | | | 5. CBFO Assessment Team Leader: M. Lea Chism | | |
| 6. Responsible Organization: WTS | | | 7. CAQ Was Discussed With: M. Akbarzadeh, G. Whiteford, D. Kump | | |
| 8. Requirement that was violated: See attached continuation sheet for details. | | | | | |
| 9. Condition Adverse to Quality: See attached continuation sheet for details. | | | | | |
| 10. Suggested Actions (Optional): None | | | | | |
| 11a. Significant CAQ | | (Yes or No): No | | | |
| 11b. Work Suspension Recommended | | (Yes or No): No | | | |
| 11c. RCRA-Related | | (Yes or No): No | | | |
| 11d. Accelerated Corrective Action Required | | (Yes or No): No | | | |
| 12. Types of Actions: Remedial: <u>X</u> Investigative: <u> </u> Root Cause: <u> </u> Actions to Preclude Recurrence: <u>X</u> | | | | | |
| 13. CAR Initiator: <u>N. Frank</u> Date: <u>9/10/03</u> | | | | | |
| 14. Response Due Date: <u>10/2/03</u> Corrective Action Plan Required: <u>NO</u> Required Corrective Action Completion Date: <u>N/A</u> | | | | | |
| 15. a. Concurrence: <u>M. Lea Chism</u> Assessment Team Leader | | <u>09-11-03</u> Date | | b. <u>N/A</u> Responsible Assistant Manager | |
| c. <u>N/A</u> Quality Assurance Manager | | Date | | | |
| 16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet | | | | | |
| 17. Acceptance of Proposed Corrective Actions: Assessment Team Leader Date | | | | | |
| 18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet) | | | | | |
| 19a. Verified By: <u> </u> Name | | <u> </u> Date | | | |
| 19b. Trend Cause Code: <u> </u> | | | | | |
| 20. Closure: <u> </u> Quality Assurance Manager Date | | | | | |

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No: 79

2. Activity No: A-03-23

3. Page 2 of 2

Block # 8 : Requirement that was violated:

WP 12-RL.01, R7, Section 4.0: "Laboratories personnel must complete the appropriate training requirements prior to performing independent work. The qualification training programs currently in use in the Radiochemistry Laboratory are the Counting Room Technician Qualification Program (CRT-01), the Radiochemistry Technician Qualification Program (TRC-01), and the Staff Radiochemist Qualification Program (SRC-01), and the Counting Room Staff Qualification Program."

WP 12-5, Rev. 9, Paragraph 7.2.5: "Records of training and qualification in radiological control are maintained to demonstrate that an individual receive appropriate information to perform the work assignment in a save manner."

WP 14-TR.01, Rev. 8, Paragraph 12.0: "Technicians and maintenance personnel will be qualified to perform the tasks associated with their specialty, or will work under the direct supervision of personnel qualified to perform the activity or task."

Block # 9 : Condition Adverse to Quality (continued)

Training records were not up to date.

1. A Counting Room Technician had not completed the qualification card (CRT-01R), yet was performing independent work.
2. The SME for Data Verification and Validation was designated on 8/22/01 by letter from the Manager. No "Oral/OJT Examination Coversheet" was in the file documenting the satisfactory oral board examination for SME.
3. A Staff Radiochemist was last qualified 3/27/01 to qualification card SRC-01. No subsequent requalification was on file. Qualification was good for two years.
4. A Radiological Engineer assigned to Station Effluent Air Monitoring had not completed qualification card RE-01, Rev. 1, yet was performing independent work.

CORRECTIVE ACTION REPORT

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| 1. CAR No: 03-080 | 2. Activity Report No: A-03-23 | 3. Page <u>1</u> of <u>2</u> |
| 4. Controlling Document: WP 12-RL.01, R7 and WP 16.2, Rev. 4 | 5. CBFO Assessment Team Leader: M. Lea Chism | |
| 6. Responsible Organization: WTS | 7. CAQ Was Discussed With: M. Akbarzadeh, G. Whiteford | |
| 8. Requirement that was violated: See attached continuation sheet for details. | | |
| 9. Condition Adverse to Quality: See attached continuation sheet for details. | | |
| 10. Suggested Actions (Optional): None | | |
| 11a. Significant CAQ (Yes or No): No 11b. Work Suspension Recommended (Yes or No): No 11c. RCRA-Related (Yes or No): No 11d. Accelerated Corrective Action Required (Yes or No): No | | |
| 12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u> | | |
| 13. CAR Initiator: <u>N. Frank</u> Date: <u>9/10/03</u> | | |
| 14. Response Due Date: <u>10/2/03</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>N/A</u> | | |
| 15. a. Concurrence: <u>Lea Chism</u> <u>09-11-03</u> b. <u>N/A</u> <div style="display: flex; justify-content: space-between; font-size: small;"> Assessment Team Leader Date Responsible Assistant Manager Date </div> <div style="display: flex; justify-content: space-between; font-size: small; margin-top: 10px;"> c. <u>N/A</u> Quality Assurance Manager Date </div> | | |
| 16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet | | |
| 17. Acceptance of Proposed Corrective Actions: <div style="display: flex; justify-content: space-between; font-size: small;"> Assessment Team Leader Date </div> | | |
| 18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet) | | |
| 19a. Verified By: _____ <div style="display: flex; justify-content: space-between; font-size: small;"> Name Date </div> | | |
| 19b. Trend Cause Code: _____ | | |
| 20. Closure: _____ <div style="display: flex; justify-content: space-between; font-size: small;"> Quality Assurance Manager Date </div> | | |

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No: 80

2. Activity No: A-03-23

3. Page 2 of 2

Block # 8 : Requirement that was violated: (continued)

WP 12-RL.01, R7, Subsection 8.4:

"All software developed by WIPP Laboratories or by subcontractors for the purpose of data manipulation or quality-related activities must be documented, manually verified, and approved according to site procedures prior to use by laboratory personnel. Revised software is subject to the same process prior to implementation. Software that is purchased from a vendor is validated and verified in accordance with site procedures."

WP 16.2, Rev. 4, Section 3.0:

"An inventory of applicable software that identifies the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software shall be maintained by the organization that owns the software (the sponsoring organization)."

WP 16.2, Rev. 4, Introduction:

"Changes to controlled software that require written notification to ETSG include the following: changes to the software name, version number, classification, exemption status, operating environment, and the person and organization responsible for the software. A new Screening Checklist (EA16-2-1-0) should be submitted for changes to status."

Block # 9 : Condition Adverse to Quality (continued)

Two counting systems had control systems different from that listed on the Controlled Software List (CSL).

1. 32-channel Alpha counter had "MCA View/Control Program", V2.6, released March 1999, Canberra. CSL had "Genie Standard User Interface" V5.2, 1/31/1998 installed in October 2000.
2. Gamma detectors had "Genie 2000 Gamma Acquisition and Analysis" V2.0, March 2, 2001, Canberra. CSL had "Genie 2000 Gamma Acquisition and Analysis", V1.4, January 29, 2000 installed in October 2000